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GR 1634

Attorney Docket: NEX89/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	LIN *et al.*	EXAMINER:	ZITOMER, S.
SERIAL NO:	09/681,508	ART UNIT:	1634
FILED:	APRIL 18, 2001	CONF NO:	4609
FOR:	APTMER BASED TWO-SITE BINDING ASSAY		

Assistant Commissioner for Patents
Washington, D.C. 20231

AMENDMENT AND REMARKS

Sir:

An Office Action was mailed in the above-captioned application on May 8, 2002. In such Office Action pending claims 1-29 were rejected. This Amendment and Remarks document is submitted in response to said Office Action.

AMENDMENT

In the Claims

Please cancel claims 1-28.

29. (amended) A method for detecting the presence of two or more target compounds in a substance which may contain said target compounds comprising:

a) exposing a substance which may contain said target compounds to capture molecules, wherein each capture molecule binds specifically to a corresponding target compound, to form a capture molecule:target compound complex;

a'

b) removing the remainder of said substance from said capture molecule:target compound complexes;

37 CFR 1.8
CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on August 8, 2002.

Signature: Tracy E. Crispino
Name: Tracy E. Crispino

c) adding to said capture molecule:target compound complexes reporter molecules; wherein each reporter molecule binds specifically to a corresponding target compound to form a capture molecule:target compound:reporter molecule complex; and

a1 cont.

d) detecting said target compounds by detection of said capture molecule:target compound:reporter molecule complexes;

wherein said capture molecules, said reporter molecules or both are a nucleic acid ligand to said target compounds.

30. (new) The method of claim 29 wherein said reporter molecule comprises a detection system.

31. (new) The method of claim 30 wherein said detection system is a nucleic acid ligand labeled with a fluorophore.

a2

32. (new) The method of claim 31 wherein said fluorophore is selected from fluorescein and Alexa.

33. (new) The method of claim 29 wherein said capture molecule is immobilized on a solid support.

34. (new) The method of claim 33 wherein said solid support is selected from a microsphere particle and a membrane.

35. (new) The method of claim 33 wherein said solid support is comprised of a spatially addressable array.

36. (new) The method of claim 29 wherein said target compounds are proteins.

37. (new) The method of claim 36 wherein one or more of said proteins are selected from thrombin and L-Selectin.

38. (new) The method of claim 29 wherein said capture molecules and reporter molecules are nucleic acid ligands.

39. (new) The method of claim 29 wherein said capture molecules are nucleic acid ligands and said reporter molecules are proteins.

40. (new) The method of claim 29 wherein said capture molecule and reporter molecule bind to separate non-overlapping sites on said target compound.

41. (new) The method of claim 29 wherein said reporter molecule binds to a site on said capture molecule:target compound complex.

42. (new) The method of claim 29 wherein said substance is a biological fluid.

43. (new) The method of claim 42 wherein said biological fluid is selected from plasma and urine.

44. (new) The method of claim 29 wherein said detection is achieved by flow cytometry.

45. (new) A method for detecting the presence of two or more target compounds in a substance which may contain said target compounds comprising:

a) identifying a nucleic acid ligand for each of said target compounds from a candidate mixture of nucleic acids, by the method comprising:

i) contacting the candidate mixture with each of said target compounds, wherein nucleic acids having an increased affinity to said targets relative to the candidate mixture may be partitioned from the remainder of the candidate mixture;

ii) partitioning the increased affinity nucleic acids from the remainder of the candidate mixture;

iii) amplifying the increased affinity nucleic acids to yield a ligand-enriched mixture of nucleic acids; and

iv) identifying said nucleic acid ligand;

b) exposing a substance which may contain said target compounds to capture molecules, wherein each capture molecule binds specifically to a corresponding target compound, to form a capture molecule:target compound complex;

c) removing the remainder of said substance from said capture molecule:target compound complexes;

d) adding to said capture molecule:target molecule complexes reporter molecules; wherein each reporter molecule binds specifically to a corresponding target compound to form a capture molecule:target compound:reporter molecule complexes; and

e) detecting said target compounds by detection of said capture molecule:target compound:reporter molecule complexes;

wherein said capture molecules, said reporter molecules or both are nucleic acid ligands to said target compounds identified by the method of step (a).

46. (new) The method of claim 45 wherein said reporter molecules comprise a detection system.

47. (new) The method of claim 46 wherein said detection system is a nucleic acid ligand labeled with a fluorophore.

48. (new) The method of claim 47 wherein said fluorophore is selected from fluorescein and Alexa.

49. (new) The method of claim 45 wherein said capture molecule is immobilized on a solid support.

50. (new) The method of claim 49 wherein wherein said solid support is selected from a microsphere particle and a membrane.

51. (new) The method of claim 49 wherein said solid support is comprised of a spatially addressable array.

52. (new) The method of claim 45 wherein said target compounds are proteins.

53. (new) The method of claim 52 wherein one or more of said proteins is selected from thrombin and L-Selectin.

54. (new) The method of claim 45 wherein said capture molecules and reporter molecules are nucleic acid ligands.

55. (new) The method of claim 45 wherein said capture molecules are nucleic acid ligands and said reporter molecules are proteins.

56. (new) The method of claim 45 wherein said capture molecules and reporter molecules bind to separate non-overlapping sites on said target compounds.

57. (new) The method of claim 45 wherein said reporter molecules bind to a site on said capture molecule:target complexes.

58. (new) The method of claim 45 wherein said substance is a biological fluid.

59. (new) The method of claim 58 wherein said biological fluid is selected from plasma and urine.

60. (new) The method of claim 45 wherein said detection is achieved by flow cytometry.

REMARKS

In response to the Office Action of May 8, 2002, claims 1-28 are canceled, claim 29 is amended and new claims 30-60 are added. Claims 1-29 were rejected under 35 U.S.C. § 112, second paragraph; claims 1-7, 14-20 and 22-27 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/41019; claims 1-3, 6, 8, 12, 13, 15-18, 20, 22, 26 and 27 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/40991; claims 1-6, 8-13, 15-20, 22-27 and 29 were rejected under 35 U.S.C. § 102(e) as being anticipated by Gold *et al.*, U.S. Patent No. 6,242,246; and claims 1, 5, 6, 12 and 13 were rejected under 35 U.S.C. § 102(e) as being anticipated by Dodge *et al.*, U.S. Patent Application Publication No. 2002/0051974, filed November 24, 1999. In the interest of furthering the prosecution of this application claims 1-28 are canceled without prejudice as to the subject matter contained therein. Each of the rejections, therefore, is discussed below with respect to claim 29 only.

Information Disclosure Statement

Included with this document is a copy of the Information Disclosure Statement and PTO Form 1449, filed June 28, 2001, together with the stamped Postcard Receipt verifying receipt by the Patent Office on July 2, 2001.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1-29 under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area which Applicants regard as their invention with a *reasonable* degree of precision and particularity. Specifically, the Examiner has raised the following objections.

a. In claims 1-14 and 29, step c) lacks antecedent basis in step a) and step d) lacks antecedent basis in step c) because "capable of binding" is a property, not an action. Additionally, step b) lacks antecedent basis in step a) because "exposing" in the latter step does not result in the formation of the "complex" of step b). As noted above claims 1-28 have been canceled. In response to this rejection, claim 29 has been amended to read "binds" rather than

"capable of binding." Additionally, claim 29 has been amended to clarify that a "capture molecule:target compound complex" is formed as a result of step a).

b. In claims 15-28, step d) lacks antecedent basis in step b). As noted above these claims have been canceled.

c. Claims 15-28 are confusing because the word "and" is missing from the penultimate line after "capture molecule". As noted above these claims have been canceled.

d. Claims 1-29 lack antecedent basis in prior steps for "said . . . complexe(s)." In response to this rejection, claim 29 has been amended as suggested by the Examiner.

e. Claims 1-29 lack antecedent basis on the preamble of the last step of "detecting said . . . complex" because the preamble recites "detecting the presence of a target compound." In response to this rejection, claim 29 has been amended to relate the last step to the preamble of the claim.

f. Claims 1-29 are confusing in lacking antecedent basis for "said target molecule" in prior recitations of "target compound." In response to this rejection claim 29 has been amended to read "target compound" throughout the claim.

g. Claims reciting "X or Y" are confusing due to the improper Markush language. In new claims 30-60 the word "and" has been used as suggested by the Examiner.

Rejections under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1-7, 14-20 and 22-27 under 35 U.S.C. § 102(b) as being anticipated by WO 96/41019 and claims 1-3, 6, 8, 12, 13, 15-18, 20, 22, 26 and 27 under 35 U.S.C. § 102(b) as being anticipated by WO 96/40991. As noted above, in the interest of furthering the prosecution of this case each of these claims have been canceled. Applicant respectfully requests that the rejections under 35 U.S.C. § 102(b) be withdrawn.

Rejections under 35 U.S.C. § 102(e)

The Examiner has rejected claims 1-6, 8-13, 15-20, 22-27 and 29 under 35 U.S.C. § 102(e) as being anticipated by Gold *et al.*, U.S. Patent No. 6,242,246 , which has a common inventor with the instant application. With respect to the Section 102(e) rejection Applicant will submit an executed Section 132 declaration as soon as one can be obtained from the inventor.

Applicant respectfully requests that this rejection be withdrawn upon submission of the declaration.

The Examiner has rejected claims 1, 5, 6, 12 and 13 under 35 U.S.C. § 102(e) as being anticipated by Dodge *et al.*, U.S. Patent Application Publication No. 2002/0051974, filed November 24, 1999. As noted above these claims have been canceled.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117 if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

Date: August 8, 2003

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